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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/589,730	06/08/2000	Dale C. Kenison	99,267	9108
26263	7590	02/23/2004	EXAMINER	
SONNENSCHN NATH & ROSENTHAL LLP P.O. BOX 061080 WACKER DRIVE STATION, SEARS TOWER CHICAGO, IL 60606-1080			LEVY, NEIL S	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

## Application No.

09/589,730

## Applicant(s)

KENISON ET AL.

## Examiner

Neil Levy

## Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12/19/03
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 59, 13-32, 41-47 & 49-64 is/are pending in the application.
- 4a) Of the above claim(s) 59, 13-32, 41-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to 49-64
- 8) ☒ Claim(s) 59, 13-32, 41-47 & 49-64 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 10-12, 33-40 and 48 are stated to have been cancelled per applicants response of 12/19/03. Accordingly, claims 5-9, 13-32, 41-47, and 49-64 are still in the case, and all claims should be presented, then, indicated as appropriate, their status-5-9, 13-32, 41-47, 52, 55, 59 and 63 were withdrawn at last office action.

No claims are currently amended.

Claims 5-9, 13-32, 41-47 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, the elected species was Melemgestrol, not tylosin in claims 52, 55, 59, 63, however we will examine tylosin there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 16.

As to the 112 rejection, applicants' holding that the implant is more than one pellet, according to Webster, does not address separation in time, and does not address a single pellet. We concur that one or more pellets, delivered in one or more sites at one or more times, constitutes an implant, and the rejection is withdrawn.

Claims 49-51, 54, 58, 61, 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al '98 in view of Ivy et al 4670249 and Shih-WO 0/25743 and further in view of Stevens et al 5874098.

The rejection of record is maintained, but extended with Stevens.

Johnson enhanced Lamb growth, with an implant of trenbolane acetate and Estradiol however, it is not clear implant had 2 separate pellets. However, the instant invention does not require simultaneous implantation.

Ivy shows separate or combination as equivalent growth hormone/growth promoter Zeranol, in Sheep implants (col. 3, lines 49-line 23, col.4), of pellet form for long action. Any anabolic growth hormone is useful (col. 3, lines 35-43), although Ivy didn't use Trenbolone or estradiol. Smith did, as equivalents for estradiol and trenbolone (p.7, top). Ivy uses both immediate release (p. 7, line 9+) and controlled release (line 18+, p. 7), biodegradable implantable pellets (p. 8, line 15). The pellets are administered separately from the same device (p.11, last paragraph). See claim 7 –the agents are different; see claim 8, see claim 10 dosages are shown at p. 16 = 12-178 mg.

Stevens also utilized, generically, growth promoting hormones growth and birth control. Hormones, are combined with antibiotics (col.5, lines 33-45) in biodegradable implant pellets as instantly claimed, in delayed and immediate release formulae (example 1, with tylosin, since Steven doesn't differentiate between the hormones, but exemplifies only bovine growth hormone (col.5, line 55) one of ordinary skill would know any of the growth an birth control hormones, as normally used in animal husbandry as growth stimulants of cattle....chickens (col.1, lines 21-24). Motivation to use the Steven's combination is that in normal use infection is an issue, as sterile injection is virtually impossible to achieve (col.1, last paragraph, col.2 top). Thus, the incorporation of the antibiotic, exemplified by a tylosin. Therefore any of the Johnson, Ivy, Shih

implants would be enhanced with tylosin or other antibiotic incorporation. The activity in combination, as claimed at claim 49, is not one subject to operator control, but merely a statement of what applicant interprets, and not of patentable weight. The particular dosage is known in the prior art cited; a function of the animal, life stage size and/or weight.

Thus, it would be obvious to one of ordinary skill in the art desiring to utilize implants of anabolic agents of Johnson, in order to enhance sheep growth, to modify the delivery as shown equivalently effective by Ivy, with separate fast and slow pellets of Shih. Shih also shows equivalence of the use of combinations, inclusive of the Johnson, Ivy, and instant agents, all in the art of animal growth enhancement; while Stevens provides motivation to combine the instant antibiotic with known growth promoting hormones in biodegradable immediate and delayed release implants.

Applicant does not have nor provided any objective evidence of criticality, nonobvious or unexpected results that the administration of the particular ingredients' or concentrations provides any greater of different level of prior art expectation as claimed. The declaration is directed to different combination than those elected, and the results, in accord with the cited art, are expected.

The selection of each ingredient is a result effective parameter chosen to obtain the desired effects. It would be obvious to vary the nature of each ingredient to optimize the effects desired.

Applicant's arguments filed 12/19/03 have been fully considered but they are not persuasive. Applicant argues the cited references don't teach both the instant growth

promotant with a supplemental agent. However, the art shows the supplemental agents and growth hormones are well known implants; whether combined in one implant or implanted at different sites and/or times, in the same animal, the concept as claimed is well known. So is the delayed or prolonged release, the use of biodegradable materials and the use of immediate release, in order to obtain immediate effects while waiting for prolonged release forms to achieve effective blood levels.

Claims 53, 56, 57, 60 and 64 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

This application contains claims 5-9, 13-32, 41-47 are drawn to an invention nonelected with traverse in Paper No. <sup>46</sup>. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is 571-272-0619. The examiner can normally be reached on Tuesday through Friday from 7a.m to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Levy/tgd

February 18, 2004



NEIL S. LEVY  
PRIMARY EXAMINER